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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,806	07/17/2003	Sylvia Daunert	50229-378	8451

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EXAMINER	
GRUN, JAMES LESLIE	
ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/620,806	DAUNERT ET AL.	
	Examiner	Art Unit	
	James L. Grun	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 8-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/20/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The amendment filed 20 March 2007 is acknowledged and has been entered. Claim 21 is newly added. Claims 1-21 remain in the case. Claims 1-5 and 8-20 have been withdrawn from further consideration as being drawn to a non-elected invention.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification is objected to and claims 6, 7, and 21 are rejected under 35 U.S.C. § 112, first paragraph, for reasons similar to those of record set forth in the prior rejection of the similar subject matter of claims 6 and 7, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, particularly the invention of the scope as is now claimed. Applicant teaches a method using reagents comprising primary antibodies specific for 6-keto-prostaglandin $F_{1\alpha}$, an aequorin-6-keto-prostaglandin $F_{1\alpha}$-conjugate, and secondary immobilized anti-immunoglobulin antibodies (see e.g. pages 13 or 15). Absent further written description and guidance from applicant one

would not be assured of the ability to make and use the invention of the scope as instantly claimed wherein merely a secondary antibody of undefined specificity is used in the kit. Perhaps applicant intended a secondary anti-immunoglobulin antibody that binds the primary antibody.

Applicant's arguments filed 20 March 2007 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 7, and 21 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 6, 7 and 21, the interrelationships of the components are not clear, e.g. it is not clear what is intended by a secondary prostaglandin $F_{1\alpha}$ immunoglobulin antibody. The examiner would suggest -- a secondary anti-immunoglobulin antibody that binds the primary antibody-- or -- a secondary anti-primary antibody antibody--.

In claim 21, "the cysteine free aequorin mutant" and "the sulfhydryl group" lack antecedent basis in claim 6, and, if the claim was intended as dependent upon claim 7, it is not clear what is being further limited because it is not known how a cysteine free aequorin mutant comprises a cysteine residue. The claim is further unclear because it is not known how a conjugate is bound to a sulfhydryl group therein.

Applicant's arguments filed 20 March 2007 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
> (c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim 6 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Pradelles et al. (Anal. Chem. 57: 1170, 1985) in view of any of Kosak (US 4,604,364), Stults (US 5,486,455), or Liotta et al. (US 5,942,407) for reasons of record.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pradelles et al. (Anal. Chem. 57: 1170, 1985) in view of any of Kosak (US 4,604,364), Stults (US 5,486,455), or Liotta et al. (US 5,942,407) as applied to claim 6 above, and further in view of Lewis et al. (Bioconjugate Chem. 11: 65, 2000) for reasons of record.

Applicant's arguments filed 20 March 2007 have been fully considered but they are not deemed to be persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this regard, applicant urges that Pradelles et al. "merely" teaches carbodiimide coupling of 6-keto-prostaglandin $F_{1\alpha}$ to a particular enzyme label and that Kosak, Stults, Liotta et al., or Lewis et al. do not specifically teach a 6-keto-prostaglandin $F_{1\alpha}$-aequorin conjugate. This is not found persuasive for the reasons of record. Label substitution is notoriously well known in the art and, as set forth in view of the direct suggestion in the references of any of Kosak, Stults, or Liotta et al., aequorin was a well known label to replace radiolabels or enzyme labels in immunoassays. As set forth, the Pradelles et al. reference, as modified by the other references, teaches assay design and reagents for a 6-keto-prostaglandin $F_{1\alpha}$ immunoassay, reagents which would have been obvious to formulate into a kit since that is conventional for convenience, economy, and reproducibility.

Applicant urges that a functional conjugate may not result for a number of reasons and, thus, that there was no reasonable expectation of success for a functional 6-keto-prostaglandin $F_{1\alpha}$-aequorin conjugate. This is not found persuasive for the reasons of record because a reasonable expectation of success, not absolute predictability, is all that is required for the sufficiency of a disclosure under 35 U.S.C. § 103, and, inter alia, the reference of Pradelles et al. teaches carbodiimide coupling of 6-keto-prostaglandin $F_{1\alpha}$ to a particular enzyme label in which the 6-keto-prostaglandin $F_{1\alpha}$ antigen retains the capacity to bind antibodies specific therefor (see pages 1171, 1172 (Fig. 2 and col. 2), and 1173 (Table II)), Kosak (US 4,604,364) teaches conventional coupling agents for use depending upon the functional groups on the ligand and on

the label and that carbodiimide was well known to couple carboxyl groups (such as on prostaglandins) to amine groups (see e.g. col. 6), Stults (see e.g. sentence bridging col. 7-8) or Liotta et al. (see e.g. cols. 7-12) teach that amine groups in aequorin were suitable for coupling and coupling thereto did not adversely affect the bioluminescence activity of the aequorin, and Lewis et al. teach a cysteine-free mutant of aequorin for use as a label.

This application contains claims 1-5 and 8-20 drawn to an invention nonelected with traverse in the paper filed 21 August 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James L. Grun, Ph.D.
June 6, 2007

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